

Remarks

I. Status of the Claims

Upon entry of the foregoing amendments, claims 22-45 are pending in the application, with claim 22 being the sole independent claim. Claims 28-35 have been withdrawn from consideration as being directed to non-elected inventions, subject to the identification of allowable subject matter in the generic or linking claim(s).

Claim 22 is sought to be amended to incorporate therein elements from claim 36. Accordingly, claim 36 is cancelled, and claims 37 and 38 have been amended to depend from claim 22. Therefore, the amendments to claims 22, 37 and 38 do not introduce new matter. Claims 43-45 are also sought to be amended. Support for the amendments to claims 43-45 may be found in the application as filed, including at page 12, lines 9-22, and page 13, line 6 to page 16, line 12. These changes introduce no new matter, and their entry is respectfully requested.

Based on the above amendments and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

II. Restriction Requirement

At page 2 of the Office Action dated March 10, 2006 (hereinafter "the Office Action"), at § 2, the Examiner has affirmed the Restriction Requirement of July 13, 2005 (hereinafter "the Restriction Requirement"). In the Restriction Requirement at page 2 the Examiner had asserted that claims 22-24 and 36-45 are generic, link Groups I-IV (represented by claims 25-35), and that the Restriction Requirement between the linked

inventions “is subject to the nonallowance of the linking claim(s), claim 22-24 and 36-45.” Upon the identification of allowable subject matter in the generic or linking claims, Applicants respectfully request that the Examiner withdraw the restriction requirement and examine the non-elected inventions, as stated at page 3 of the Restriction Requirement and in accordance with M.P.E.P. § 809.

III. Objection to the Oath or Declaration and to the Application Data Sheet

At page 3, §§ 4-5, of the Office Action the Examiner has objected to the Declaration and to the Application Data Sheet for errors therein. Applicants provide herewith a corrected Application Data Sheet and executed Declaration, accommodating the Examiner’s objections.

IV. Objection to the Specification

At page 3, § 6 of the Office Action the Examiner has objected to the first paragraph of the specification. Applicants have amended the first paragraph of the specification and have thereby accommodated the Examiner’s objection.

V. The Information Disclosure Statement

The Examiner has initialed Applicants’ Form PTO-1449, indicating that all documents submitted in the Information Disclosure Statement have been considered, with the exceptions of Documents AL1 and AR3.

At page 4, § 7 of the Office Action the Examiner has stated that JP 9000069 (Document AL1) was not considered because an English language translation was not

provided. The Examiner has considered Document AT1, the unverified English language abstract of Document AL1, which was provided in accordance with 37 C.F.R. § 1.98(a)(3). However, M.P.E.P. § 609.05(b) requires the Examiner to consider the foreign-language art insofar as it may be understood on its face (figures, formulas, etc.). Applicants respectfully request that the Examiner consider document AL1 in accordance with M.P.E.P. § 609.05(b).

The Examiner has stated that the International Search Report (Document AL3) was not considered, although all art cited therein was considered by the Examiner. Document AL3 was provided out of an overabundance of caution, especially in view of the decision in *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358 (Fed. Cir. 2003).

VI. Rejections under 35 U.S.C. § 112, first paragraph, written description

At pages 4-6, § 8 of the Office Action the Examiner has rejected claims 22-24 and 36-45 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in art that the inventor had possession of the claimed invention. Summarizing the rejection, the Examiner asserts that:

Applicants fail to describe a representative number of polynucleotide sequences encoding a GA 2-oxidase enzyme falling within the scope of the claimed genus of polynucleotides. Applicants only describe a single cDNA sequence of SEQ ID NO:1. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the GA 2-oxidase enzyme, it remains unclear what features identify a *Phaseolus* GA 2-oxidase enzyme. Since the genus of GA 2-oxidase enzymes has not been

described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Office Action at page 6. Applicants respectfully traverse the rejection.

The Federal Circuit in *Eli Lilly* set forth several *alternative* tests for whether a claimed genus is adequately described, including the “representative number of species” test and the “common structural features” test. *Regents of the Univ. of Calif. v. Eli Lilly & Co.*, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). The court also stated that “[w]e will not speculate in what *other* ways a broad genus of genetic material may be properly described.” *Id.* (emphasis added). There is no fixed set of tests for whether a claimed genus is adequately described. Instead, the determination of compliance with the written description requirement is a fact-based one and, in cases subsequent to *Eli Lilly*, the Federal Circuit has limited the holding in *Eli Lilly* to its particular set of facts. *See Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1320 (Fed. Cir. 2003); *Amgen Inc. v. Hoechst Marion Roussel Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002).

Ultimately, the question of whether a claimed invention is adequately described depends on whether one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention in the specification as filed. *See Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1320 (Fed. Cir. 2003) (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991)); *see also* M.P.E.P. § 2163.02.

The present specification, at Examples 1 and 2, describes the isolation of a GA 2-oxidase from *Phaseolus coccineus* by screening a genomic library for GA 2-oxidase

enzymatic activity. This clone was then sequenced to obtain the nucleotide (SEQ ID NO:1) and amino acid sequence (SEQ ID NO:2) of the *Phaseolus coccineus* GA 2-oxidase PcGA2ox1. Example 3 describes how the PcGA2ox1 sequence was then used to isolate three GA 2-oxidases from *Arabidopsis thaliana*, AtGA2ox1, AtGA2ox2, and AtGA2ox3. Subsequent to the filing date, the DNA sequence of GA 2-oxidase has been used to isolate GA 2-oxidases from numerous plant species, including pea, rice, spinach, poplar and oleander. *See, e.g.* Exhibits A-E.

In view of these facts, Applicants assert that the originally-filed disclosure conveys to those of ordinary skill in the art that Applicants had possession of that which is claimed. Subject matter that “might fairly be deduced from the original application” is considered to be described in the application as filed. *Acme Highway Products Corp. v. D.S. Brown Co.*, 431 F.2d 1074, 1080 (6th Cir. 1970) (citations omitted), *cert. denied*, 401 U.S. 956 (1971), *followed by Westphal v. Fawzi*, 666 F.2d 575, 577 (C.C.P.A. 1981). The written description requirement of 35 U.S.C. § 112, first paragraph, is met “if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an [applicant] had possession of the concept of what is claimed,” *id.*, *i.e.*, “[i]f a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification” *In re Alton*, 37 U.S.P.Q.2d 1578, 1584 (Fed. Cir. 1996). As it a matter of *fact* that the description of GA 2-oxidase from *Phaseolus coccineus* has been used to identify GA 2-oxidases from unrelated species of plant, Applicants assert that the disclosure already conveys to those of

ordinary skill that Applicants had possession of at least the genus of GA 2-oxidases from *Phaseolus*.

Moreover, a comparison of the present facts with those at issue in *Eli Lilly* supports Applicants' assertion. In *Eli Lilly*, the court found that a specification describing the *rat* insulin gene did not offer sufficient written description to demonstrate possession of the insulin gene from *humans*, an organism unrelated to rats. In the present case, not only have Applicants already provided a specific PcGA2Ox1 sequence, but have *shown* that this sequence put them in possession of GA 2-oxidases from an unrelated plant species, such as *Arabidopsis*. This would be equivalent in the *Eli Lilly* context to sequencing the rat and human insulins, and then being rejected for claims to "rodent" insulins for failing to isolate the mouse insulin gene. One of ordinary skill in the art, however, would believe that isolation of the *Phaseolus coccineus* PcGA2Ox1 would reasonably place one in possession of the genus of *Phaseolus* GA 2-oxidase genes, especially in view of the isolation of GA 2-oxidases from unrelated plants.

In any event, if the *Eli Lilly* standards *are* applied to the present case, Applicants respectfully assert that the present disclosure provides common structural features *and* a sufficient number of representative species. The Examiner asserts that Applicants have not identified specific structural features. Applicants assert that provision of the linear sequence is sufficient "structural features" for those of ordinary skill in the art. This is especially so as the PcGA2Ox1 sequence was used to isolate the GA 2-oxidases from *Arabidopsis* and that these four sequences provided sufficient structural information to isolate GA 2-oxidases from additional plants. Accordingly, Applicants assert that provision of the linear sequence of PcGA2ox1 provides sufficient "common structural

features" to those of ordinary skill in the art, and that this is even more so by Applicants provision of four (4) GA 2-oxidase species. Accordingly, those of ordinary skill in the art would consider that Applicants had possession of that which is claimed.

Under the "representative species" test of *Eli Lilly*, Applicants also respectfully assert that the cloning and identification of a single *Phaseolus coccineus* GA 2-oxidase meets the written description requirement. A single species was recently held to be sufficient to comply with the written description requirements of 35 U.S.C. § 112, first paragraph. *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052 (Fed. Cir. 2005). Accordingly, Applicants assert that they have provided a sufficient number of representative species, meeting this alternative *Eli Lilly* standard.

For at least the above reasons, Applicants respectfully believe that the Examiner's rejections have been overcome, and request reconsideration and withdrawal of the present rejection under 35 U.S.C. § 112, first paragraph, written description.

VII. Rejections under 35 U.S.C. § 112, first paragraph, enablement

At pages 6-9, § 9 of the Office Action the Examiner has rejected claims 22-24 and 36-45 under 35 U.S.C. § 112, first paragraph, alleging that the claims exceed the scope of enablement provided by the specification. The Examiner's rejection centers on the breadth of different GA 2-oxidases which can be used in plants. Applicants respectfully traverse the rejection. The rejection comprises several aspects, which will be dealt with in turn.

As an initial matter, Applicants remind the Examiner that in order to enable a claimed invention, a specification need not even disclose working examples. "Nothing

more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples.” *In re Wright*, 27 U.S.P.Q.2d 1510, 1561 (Fed. Cir. 1999); *see also In re Borkowski*, 422 F.2d 904, 908 (C.C.P.A. 1970) (“a specification need not contain a working example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation.”); *In re Long*, 151 U.S.P.Q. 640, 642 (C.C.P.A. 1966) (“absence of a working example does not in and of itself compel the conclusion that a specification does not satisfy the requirements of section 112.”). Rather, the enablement requirement of 35 U.S.C. § 112, first paragraph, is satisfied if the claimed invention is enabled so that any person skilled in the art can make and use the invention without undue experimentation. *See In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988).

(a) *Biemelt et al.* is not evidence of lack of enablement.

At page 8, the Examiner cites *Biemelt et al.* (Plant Physiology 135: 254-256 (2004), hereinafter “*Biemelt*”) as post-filing evidence of unexpected results, stating that:

Biemelt [] disclose Arabidopsis plants transformed with a nucleic acid from Arabidopsis [sic] encoding the AtGA2-ox protein, not only produced dwarf plants, but said plants also exhibited a down regulation of lignin biosynthetic genes (abstract) and a reduction in plant biomass.

Applicants note that the sole independent claim 22 recites that “said [gibberellin 2-oxidase enzyme] is expressed at a level sufficient to inhibit growth in a plant grown from said transformed plant cells.” None of the claims makes reference to lignin biosynthesis or biomass. Thus *Biemelt*’s disclosure of down-regulation of lignin genes and reduced

biomass is irrelevant to enablement of the claims. Instead, Biemelt is post-filing evidence of enablement of the presently claimed invention.

The present specification describes the cloning of GA 2-oxidases from *Phaseolus* and *Arabidopsis*, *Agrobacterium*-mediated transformation of *Phaseolus* GA 2-oxidase into plant cells and production of transgenic *Arabidopsis* and *Nicotiana sylvestris* plants which exhibit dwarf phenotypes.

Biemelt follows the teachings of the present specification. First, Biemelt refers to publications of the present inventors for the first isolation of GA 2-oxidase, first from *Phaseolus*, then *Arabidopsis*, and that the GA 2-oxidase has since been identified by sequence information from the pea and rice genome. *See* page 225, column 1. Using sequence information, Biemelt independently cloned *Arabidopsis* GA 2-oxidase and, through *Agrobacterium*-mediated transformation, produced transgenic *Nicotiana sylvestris* with dwarf phenotypes. Accordingly, Biemelt is evidence that the present specification provides those of ordinary skill in the art with sufficient disclosure and teachings to practice the claimed invention.

(b) Applicants have disclosed to those of ordinary skill in the art how to make or isolate sequences encompassed by the claims

At page 9, first paragraph, of the Office Action the Examiner asserts that:

Applicants have not disclosed how one makes or isolates any of the sequences that are encompassed by Applicants' broad claims. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences.

Applicants respectfully disagree. The enablement requirement of 35 U.S.C. § 112, first paragraph, is satisfied if the claimed invention is enabled so that any person skilled in the art can make and use the invention without undue experimentation.

The specification describes how to clone GA 2-oxidase genes by homology, PCR (*see, e.g.*, page 5, line 10 to page 6, line 20; page 13, lines 6-10), enzymatic activity (*see, e.g.*, page 15), antibodies (*see, e.g.*, page 16, lines 14-17), and then provides specific working examples of the cloning of four (4) different GA 2-oxidases from two (2) unrelated plant species (*see* Examples 1-3). Applicants therefore assert that the specification enables those of ordinary skill to clone additional GA 2-oxidases.

Moreover, even if such evidence was insufficient, the post-filing art is replete with evidence that those of ordinary skill in the art, following the teachings of the present invention, have been able to clone GA 2-oxidases from a wide variety of species and, further, use such cloned oxidases in transgenic plants. *See, e.g.*, Exhibits A-E. Accordingly, the present specification enables those of ordinary skill in the art to make and use the presently claimed invention with a broad range of GA 2-oxidases.

(c) Expression of the nucleic acid is enabled.

At page 9 of the Office Action the Examiner asserts that the claims are not enabled because they do not recite that the nucleic acid is operatively linked to the promoter, and that correct expression in the absence of the promoter would require undue experimentation. Applicants respectfully disagree, asserting that the Examiner has not met the burden of showing undue experimentation. However, solely to advance

prosecution, claim 22 has been amended to recite that the nucleic acid is operatively linked to a promoter, thereby accommodating the Examiner's rejection.

(d) Concluding remarks

For at least the reasons provided herein, Applicants respectfully believe that the scope of the present claims are well within the enablement provided by the specification. Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

VIII. Rejections under 35 U.S.C. § 101

In the Office Action at page 10, § 10, the Examiner has rejected claims 43-45 under 35 U.S.C. § 101 for allegedly encompassing non-statutory subject matter. Applicants respectfully traverse the rejection. Solely to advance prosecution, however, and not in acquiescence to the rejection, Applicants have amended claims 43-45 to recite that the plant or plant material comprises the nucleic acid construct. As this amendment was suggested by the Examiner, Applicants respectfully believe that the rejection under 35 U.S.C. § 101 has been overcome and request that the Examiner reconsider and withdraw the rejection.

IX. Other Matters

At page 11, § 11 of the Office Action the Examiner has stated that claims 22-27 and 36-45 are free of the prior art and, at § 12, that claims 25-27 would be allowable if re-written in independent form. Applicants thank the Examiner for the identification of otherwise allowable subject matter and for indicating that that the claimed invention is

free of the art. However, Applicants have not rewritten those claims in independent form at this time. Rather, Applicants respectfully believe that all claims are allowable, in view of the foregoing amendments and remarks.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants also request that the Examiner withdraw the pending restriction requirement and examine claims 28-35. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Simon J. Elliott, Ph.D.
Agent for Applicants
Registration No. 54,083

Date: July 13, 2006

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

548586_1.DOC